IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AVANIR PHARMACEUTICALS, INC., AVANIR HOLDING COMPANY, and CENTER FOR NEUROLOGIC STUDY,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
SANDOZ, INC.,	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Avanir Pharmaceuticals, Inc. ("Avanir Pharmaceuticals"), Avanir Holding Company, and Center for Neurologic Study ("CNS") (collectively, "Plaintiffs"), by their undersigned attorneys, for its Complaint against Defendant Sandoz, Inc. ("Sandoz"), allege as follows:

Nature of Action

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. §100, *et seq.*, including 35 U.S.C. § 271(a), (b), (c), and (e), and for a declaratory judgment of patent infringement under 28 U.S.C. §§ 2201 and 2202, arising from Sandoz's acquisition of an Abbreviated New Drug Application ("ANDA") filed with the United States Food and Drug Administration ("FDA") seeking approval to commercially market a generic version of Avanir's NUEDEXTA® drug product prior to the expiration of United States Patent Nos. 7,659,282 ("the '282 patent"), 8,227,484 ("the '484 patent"), and RE38,115 ("the '115 patent") (collectively, "the Patents-in-Suit").

The Parties

2. Plaintiff Avanir Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 20 Enterprise, Suite 200, Aliso Viejo, California 92656.

3. Plaintiff Avanir Holding Company is a corporation organized and existing under the laws of the State of California, having a principal place of business at 20 Enterprise, Suite 200, Aliso Viejo, California 92656. Avanir Holding Company is a wholly-owned subsidiary of Avanir Pharmaceuticals.

4. Plaintiff Center for Neurologic Study is a not-for-profit corporation organized and existing under the laws of the State of California, having a principal place of business at 9850 Genese Avenue, Suite 320, La Jolla, California 92037.

5. On information and belief, Defendant Sandoz, Inc. is a corporation organized and existing under the laws of the State of Colorado, having its principal place of business at 506 Carnegie Center, Suite 400, Princeton, New Jersey 08540.

6. On information and belief, Sandoz is a pharmaceutical company that formulates, manufactures, packages, and markets generic drug products for distribution in the District of Delaware and throughout the United States.

Jurisdiction and Venue

7. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

8. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

9. This Court has personal jurisdiction over Sandoz because, among other things, Sandoz markets and sells generic drugs throughout the United States and within the State of

Delaware, and therefore purposefully avails itself of the privilege of conducting activities within the State of Delaware. On information and belief, Sandoz is registered with the Delaware Board of Pharmacy as a "Distributor/Manufacturer" and "Pharmacy-Wholesale" of drug products.

10. On information and belief, Sandoz has derived substantial revenue from sales of pharmaceutical products in Delaware.

11. On information and belief, Sandoz has previously availed itself of this forum for the purpose of litigating its patent infringement disputes by, *inter alia*, admitting or submitting to the jurisdiction of this Court and asserting counterclaims in other civil actions initiated in this jurisdiction. *See, e.g, Abbott v. Sandoz*, C.A. No. 12-00103 (D. Del.) and *Pfizer v. Sandoz*, C.A. No. 11-01284 (D. Del.).

The Patents-in-Suit

12. On February 9, 2010, the United States Patent and Trademark Office ("USPTO") duly and lawfully issued the '282 patent, entitled "Pharmaceutical Compositions Comprising Dextromethorphan and Quinidine for the Treatment of Neurological Disorders" to inventors Gerald Yakatan, James Berg, Laura Pope, and Richard Smith. Avanir Pharmaceuticals is the assignee of the '282 patent. The '282 patent expires on August 13, 2026. A copy of the '282 patent is attached hereto as Exhibit A.

13. On May 6, 2003, the USPTO duly and lawfully issued the '115 patent, entitled "Dextromethorphan and an Oxidase Inhibitor for Treating Intractable Conditions" to inventors Richard Smith and Jonathan Licht. CNS is the assignee of the '115 patent. Avanir Holding Company is an exclusive licensee of the '115 patent, and Avanir Pharmaceuticals is an exclusive sub-licensee of the '115 patent. The '115 patent expires on January 26, 2016. A copy of the '115 patent is attached hereto as Exhibit B.

14. On July, 24, 2012, the USPTO duly and lawfully issued the '484 patent, entitled "Pharmaceutical Compositions Comprising Dextromethorphan and Quinidine for the Treatment of Neurological Disorders" to inventors Gerald Yakatan, James Berg, Laura Pope, and Richard Smith. Avanir Pharmaceuticals is the assignee of the '484 patent. The '484 patent expires on July 17, 2023. A copy of the '484 patent is attached hereto as Exhibit C.

The NUEDEXTA® Drug Product

15. Avanir Pharmaceuticals holds an approved New Drug Application ("NDA") under Section 505(a) of the Federal Food Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 355(a), for dextromethorphan hydrobromide/quinidine sulfate capsules (NDA No. 21-879), which it sells under the trade name NUEDEXTA®. The claims of the Patents-in-Suit cover, *inter alia*, pharmaceutical formulations containing dextromethorphan hydrobromide/quinidine sulfate or methods of using same.

16. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the Patents-in-Suit are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to NUEDEXTA®.

Acts Giving Rise to this Suit

17. Watson Pharmaceuticals, Inc., Watson Laboratories, Inc., and Watson Pharma Inc. (collectively, "Watson") filed ANDA No. 203538 seeking the FDA's approval to engage in the commercial use, manufacture, sale, offer for sale or importation of 20 mg dextromethorphan hydrobromide/10 mg quinidine sulfate capsules ("Watson's Proposed Product") before the Patents-in-Suit expire.[1]

[1] Avanir previously initiated a patent infringement suit against Watson in this District based on Watson's filing of ANDA No. 203538, the same ANDA that has now been

18. Upon information and belief, in connection with the filing of its ANDA, Watson provided written certifications to the FDA, pursuant to Section 505 of the FFDCA, alleging that the claims of the Patents-in-Suit are invalid and/or will not be infringed by the activities described in ANDA No. 203538.

19. No earlier than January 26, 2012, Watson sent written notice of its ANDA certification relating to the '282 and '115 patents to Avanir Pharmaceuticals ("Watson's First Notice Letter"). Watson's First Notice Letter alleged that the claims of the '282 and '115 patents are invalid, unenforceable, and/or will not be infringed by the activities described in ANDA No. 203538. Watson's First Notice Letter also informed Avanir Pharmaceuticals that Watson sought approval to market Watson's Proposed Product before the expiration of the '282 and '115 patents..

20. Pursuant to 21 U.S.C. § 355(j)(5)(B)(iii), Plaintiffs initiated a patent infringement suit against Watson in this District within 45 days of receiving Watson's First Notice Letter, thereby invoking the 30-month stay of FDA approval of ANDA No. 203538. *Avanir Pharms., Inc. et al. v. Actavis South Atlantic LLC, et al.*, C.A. No. 11-704-LPS (Consolidated). The 30-month stay attaching to ANDA No. 203538 continues to run through July 27, 2014.

21. No earlier than August 15, 2012, Watson sent written notice of its ANDA certification relating to the '484 patent to Avanir Pharmaceuticals ("Watson's Second Notice Letter"). Watson's Second Notice Letter alleged that the claims of the '484 patent are invalid and/or will not be infringed by the activities described in ANDA No. 203538. Watson's Second Notice Letter also informed Avanir Pharmaceuticals that Watson sought approval to market Watson's Proposed Product before the expiration of the '484 patent.

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acquired by Sandoz and is the subject of this Complaint. *Avanir Pharms., Inc. et al. v. Actavis South Atlantic LLC, et al.*, C.A. No. 11-704-LPS (Consolidated).

22. Upon information and belief, on November 6, 2012, Watson executed an Asset Purchase Agreement with Sandoz, by which Watson transferred to Sandoz all of Watson's rights and interests in ANDA No. 203538.

23. Upon information and belief, Sandoz is currently seeking FDA approval to market the generic product that is the subject of ANDA No. 203538 ("Sandoz's Proposed Product") before the Patents-in-Suit expire.

24. Upon information and belief, Sandoz has maintained written certifications to the FDA, pursuant to Section 505 of the FFDCA, alleging that the claims of the Patents-in-Suit are invalid and/or will not be infringed by the activities described in ANDA No. 203538.

Count I: Infringement of the '282 Patent Under 35 U.S.C. § 271(e)(2)(A)

25. Avanir Pharmaceuticals repeats and realleges the allegations of paragraphs 1-24 as though fully set forth herein.

26. Sandoz's acquisition and maintenance of ANDA No. 203538 and seeking of FDA approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of dextromethorphan hydrobromide/quinidine sulfate capsules, prior to the expiration of the '282 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

27. There is a justiciable controversy between Avanir Pharmaceuticals and Sandoz as to the infringement of the '282 patent.

28. Unless enjoined by this Court, upon FDA approval of ANDA No. 203538, Sandoz will infringe the '282 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Sandoz's Proposed Product in the United States.

29. Unless enjoined by this Court, upon FDA approval of ANDA No. 203538, Sandoz will induce infringement of the '282 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Sandoz's Proposed Product in the United States. On information and belief, upon FDA approval of ANDA No. 203538, Sandoz will intentionally encourage acts of direct infringement with knowledge of the '282 patent and knowledge that its acts are encouraging infringement.

30. Unless enjoined by this Court, upon FDA approval of ANDA No. 203538, Sandoz will contributorily infringe the '282 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Sandoz's Proposed Product in the United States. On information and belief, Sandoz has had and continues to have knowledge that Sandoz's Proposed Product is especially adapted for a use that infringes the '282 patent and that there is no substantial non-infringing use for Sandoz's Proposed Product.

31. Avanir Pharmaceuticals will be substantially and irreparably damaged and harmed if Sandoz's infringement of the '282 patent is not enjoined.

32. Avanir Pharmaceuticals does not have an adequate remedy at law.

33. This case is an exceptional one, and Avanir Pharmaceuticals is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count II: Declaratory Judgment of Infringement of the '282 Patent

34. Avanir Pharmaceuticals repeats and realleges the allegations of paragraphs 1-33 as though fully set forth herein.

35. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 et seq., including 35 U.S.C. § 271(a), (b), and (c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201, 2202.

36. There is an actual case or controversy such that the Court may entertain Avanir Pharmaceuticals' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

37. On information and belief, Sandoz has made, and will continue to make, substantial preparation in the United States to manufacture, offer to sell, sell and/or import Sandoz's Proposed Product prior to the expiration of the '282 patent.

38. On information and belief, if the FDA approves ANDA No. 203538, Sandoz and/or its agents plan to begin marketing, selling, and offering to sell Sandoz's Proposed Product in the United States immediately or soon after receiving FDA approval. Such conduct will constitute infringement, either literally or under the doctrine of equivalents, of one or more claims of the '282 patent under 35 U.S.C. § 271(a), (b), and/or (c).

39. Unless enjoined by this Court, upon FDA approval of ANDA No. 203538, Sandoz will infringe the '282 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Sandoz's Proposed Product in the United States.

40. Unless enjoined by this Court, upon FDA approval of ANDA No. 203538, Sandoz will induce infringement of the '282 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Sandoz's Proposed Product in the United States. On information and belief, upon FDA approval of ANDA No. 203538, Sandoz will intentionally encourage acts of direct infringement with knowledge of the '282 patent and knowledge that its acts are encouraging infringement.

41. Unless enjoined by this Court, upon FDA approval of ANDA No. 203538, Sandoz will contributorily infringe the '282 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Sandoz's Proposed Product in the United States. On

information and belief, Sandoz has had and continues to have knowledge that Sandoz's Proposed Product is especially adapted for a use that infringes the '282 patent and that there is no substantial non-infringing use for Sandoz's Proposed Product.

42. Avanir Pharmaceuticals is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's Proposed Product prior to the expiration of the '282 patent by Sandoz will constitute direct infringement, contributory infringement, and/or active inducement of infringement of the '282 patent.

43. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Avanir Pharmaceuticals and Sandoz as to liability for the infringement of the '282 patent. Sandoz's actions have created in Avanir Pharmaceuticals a reasonable apprehension of irreparable harm and loss resulting from Sandoz's threatened imminent actions.

Count III: Infringement of the '115 Patent Under 35 U.S.C. § 271(e)(2)(A)

44. Plaintiffs repeat and reallege the allegations of paragraphs 1-43 as though fully set forth herein.

45. Sandoz's acquisition and maintenance of ANDA No. 203538 and seeking of FDA approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of dextromethorphan hydrobromide/quinidine sulfate capsules, prior to the expiration of the '115 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

46. There is a justiciable controversy between the parties hereto as to the infringement of the '115 patent.

47. Unless enjoined by this Court, upon FDA approval of ANDA No. 203538, Sandoz will infringe the '115 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Sandoz's Proposed Product in the United States.

48. Plaintiffs will be substantially and irreparably damaged and harmed if Sandoz's infringement of the '115 patent is not enjoined.

49. Plaintiffs do not have an adequate remedy at law.

50. This case is an exceptional one, and Plaintiffs are entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count IV: Declaratory Judgment of Infringement of the '115 Patent

51. Plaintiffs repeat and reallege the allegations of paragraphs 1-50 as though fully set forth herein.

52. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 et seq., including 35 U.S.C. § 271(a), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201, 2202.

53. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

54. On information and belief, Sandoz has made, and will continue to make, substantial preparation in the United States to manufacture, offer to sell, sell and/or import Sandoz's Proposed Product prior to the expiration of the '115 patent.

55. On information and belief, if the FDA approves ANDA No. 203538, Sandoz and/or its agents plan to begin marketing, selling, and offering to sell Sandoz's Proposed Product in the United States immediately or soon after receiving FDA approval. Such conduct will

constitute infringement, either literally or under the doctrine of equivalents, of one or more claims of the '115 patent under 35 U.S.C. § 271(a).

56. Unless enjoined by this Court, upon FDA approval of ANDA No. 203538, Sandoz will infringe the '115 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Sandoz's Proposed Product in the United States.

57. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's Proposed Product prior to the expiration of the '115 patent by Sandoz will constitute direct infringement of the '115 patent.

58. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Sandoz as to liability for the infringement of the '115 patent. Sandoz's actions have created in Plaintiffs a reasonable apprehension of irreparable harm and loss resulting from Sandoz's threatened imminent actions.

Count V: Infringement of the '484 Patent Under 35 U.S.C. § 271(e)(2)(A)

59. Avanir Pharmaceuticals repeats and realleges the allegations of paragraphs 1-58 as though fully set forth herein.

60. Sandoz's acquisition and maintenance of ANDA No. 203538 and seeking of FDA approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of dextromethorphan hydrobromide/quinidine sulfate capsules, prior to the expiration of the '484 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

61. There is a justiciable controversy between Avanir Pharmaceuticals and Sandoz as to the infringement of the '484 patent.

62. Unless enjoined by this Court, upon FDA approval of ANDA No. 203538, Sandoz will infringe the '484 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Sandoz's Proposed Product in the United States.

63. Unless enjoined by this Court, upon FDA approval of ANDA No. 203538, Sandoz will induce infringement of the '484 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Sandoz's Proposed Product in the United States. On information and belief, upon FDA approval of ANDA No. 203538, Sandoz will intentionally encourage acts of direct infringement with knowledge of the '484 patent and knowledge that its acts are encouraging infringement.

64. Unless enjoined by this Court, upon FDA approval of ANDA No. 203538, Sandoz will contributorily infringe the '484 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Sandoz's Proposed Product in the United States. On information and belief, Sandoz has had and continues to have knowledge that Sandoz's Proposed Product is especially adapted for a use that infringes the '484 patent and that there is no substantial non-infringing use for Sandoz's Proposed Product.

65. Avanir Pharmaceuticals will be substantially and irreparably damaged and harmed if Sandoz's infringement of the '484 patent is not enjoined.

66. Avanir Pharmaceuticals does not have an adequate remedy at law.

67. This case is an exceptional one, and Avanir Pharmaceuticals is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count VI: Declaratory Judgment of Infringement of the '484 Patent

68. Avanir Pharmaceuticals repeats and realleges the allegations of paragraphs 1-67 as though fully set forth herein.

69. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 et seq., including 35 U.S.C. § 271(a), (b), and (c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201, 2202.

70. There is an actual case or controversy such that the Court may entertain Avanir Pharmaceuticals' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

71. On information and belief, Sandoz has made, and will continue to make, substantial preparation in the United States to manufacture, offer to sell, sell and/or import Sandoz's Proposed Product prior to the expiration of the '484 patent.

72. On information and belief, if the FDA approves ANDA No. 203538, Sandoz and/or its agents plan to begin marketing, selling, and offering to sell Sandoz's Proposed Product in the United States immediately or soon after receiving FDA approval. Such conduct will constitute infringement, either literally or under the doctrine of equivalents, of one or more claims of the '484 patent under 35 U.S.C. § 271(a), (b), and/or (c).

73. Unless enjoined by this Court, upon FDA approval of ANDA No. 203538, Sandoz will infringe the '484 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Sandoz's Proposed Product in the United States.

74. Unless enjoined by this Court, upon FDA approval of ANDA No. 203538, Sandoz will induce infringement of the '484 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Sandoz's Proposed Product in the United States. On information and belief, upon FDA approval of ANDA No. 203538, Sandoz will intentionally encourage acts of direct infringement with knowledge of the '484 patent and knowledge that its acts are encouraging infringement.

75. Unless enjoined by this Court, upon FDA approval of ANDA No. 203538, Sandoz will contributorily infringe the '484 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Sandoz's Proposed Product in the United States. On information and belief, Sandoz has had and continues to have knowledge that Sandoz's Proposed Product is especially adapted for a use that infringes the '484 patent and that there is no substantial non-infringing use for Sandoz's Proposed Product.

76. Avanir Pharmaceuticals is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's Proposed Product prior to the expiration of the '484 patent by Sandoz will constitute direct infringement, contributory infringement, and/or active inducement of infringement of the '484 patent.

77. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Avanir Pharmaceuticals and Sandoz as to liability for the infringement of the '484 patent. Sandoz's actions have created in Avanir Pharmaceuticals a reasonable apprehension of irreparable harm and loss resulting from Sandoz's threatened imminent actions.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A Judgment be entered that Sandoz has infringed each of the Patents-in-Suit under 35 U.S.C. § 271(e)(2)(A) by acquiring and maintaining ANDA No. 203538 and seeking FDA approval to commercially manufacture, use, offer for sale, sell, or import into the United States Sandoz's Proposed Product prior to the expiration of the Patents-in-Suit;

B. An Order under 35 U.S.C. § 271(e)(4)(A) that the effective date of FDA approval of ANDA No. 203538 be a date that is not earlier than the expiration of the Patents-in-Suit, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

C. A Declaration that Sandoz's commercial manufacture, use, offer for sale, sale, or importation into the United States of Sandoz's Proposed Product prior to the expiration of the Patents-in-Suit would constitute infringement of the Patents-in-Suit under 35 U.S.C. § 271 (a), (b), and/or (c), as set forth above;

D. Preliminary and permanent injunctions enjoining Sandoz and its officers, agents, attorneys and employees, and those acting in privity or concert with them, from making, using, selling, offering to sell, or importing Sandoz's Proposed Product until after the expiration of the Patents-in-Suit, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

E. A permanent injunction be issued, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Sandoz, its officers, agents, attorneys and employees, and those acting in privity or concert with them, from practicing any methods claimed in the '282 and '484 patents, or from actively inducing or contributing to the infringement of any claims of the '282 and '484 patents, until after the expiration of the '282 and '484 patents, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

F. If Sandoz engages in the commercial manufacture, use, importation into the United States, sale, or offer for sale of Sandoz's Proposed Product prior to the expiration of the Patents-in-Suit, a Judgment awarding damages to Plaintiffs resulting from such infringement, together with interest;

G. Attorneys' fees in this action as an exceptional case pursuant to 35 U.S.C. § 285;

H. Costs and expenses in this action; and

I. Such further and other relief as this Court may deem just and proper.

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